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09/893,510

06/29/2001

Peter Forsell

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04/27/2004

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EXAMINER

LANDREM, KAMRIN R

ART UNIT

PAPER NUMBER

3738

15

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/893,510

Applicant(s)

FORSELL, PETER

Examiner

Kamrin R. Landrem

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-34,48-51,61-67,71-83 and 93-255 is/are pending in the application.
- 4a) Of the above claim(s) 100-248 and 251-253 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-34,48-51,61-67,71-83,93-99,249,250,254 and 255 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 100-248, 251, 252, and 253 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 100-173 and 190-200 are directed to non-elected Species VII (Figure 7), which comprises an external energy source. Claims 174-189 and 201-246 are directed to non-elected Species VII (Figure 7), which comprises a data communicator (transceiver). Claims 251 and 252 are also directed to non-elected Species VII, which comprises a sensor (see reference number 54 in Figure 7). Claim 253 is directed to nonelected Species VI (Figure 6), which comprises an accumulator (energy storage device 240)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 100-248, 251, 252, and 253 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 6-34, 48-51, 61-67, 71-83, 93-99, 249,250, 254 and 255 are hereby considered for examination purposes.

Examiners Note: The examiner would like to point out that non-elected claims 226-237 are improperly dependent. It is unclear what claim 226 depends from. See claim 226.

Claim Objections

Claims 249-250 are objected to because of the following informalities: The word feces is misspelled "faeces" in line 6. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,6-17,20-34,49-51,61-67,71,72,75,80-83,93,95-99,249,250 are rejected under 35 U.S.C. 102(e) as being anticipated by Bardy (USPN 6,238,423).

Bardy discloses an apparatus 8 for treating constipation and intestine dysfunction comprising an electrical stimulator 10, electrical conductors 14 that directly stimulate the muscles to contract, an internal power supply 48 and a programmable external control device 62 for controlling the release of electrical energy from the power supply. The stimulation device 10 may be controlled by another external control means is activated by a magnet causing an electromagnetic field to move the switch (10:52-59). Electrical conductors may be connected to the muscle tissue by means such as suturing and stapling. As shown in Figure 6 and 7 the control device can control the stimulation device to vary the intensity of the stimulation of the muscle

Art Unit: 3738

over time. The control device and stimulation device can be used to provide contractions in the area of the rectum to help cause the muscles associated with the anus to relax thereby helping the patient to defecate (14:56-65). Bardy further discloses an implantable sensing device 24 for sensing the physical parameters within the patient (7:27+). The sensing means is capable of detecting pressure (8:12+). The control device may also be a programmable internal device 54 such as a microprocessor (10:55) for controlling the stimulation device in response to signals from the sensors 24. The controller 54 stores information (9:63-64) relating to physical parameters and work station 62 is also capable of storing collected information. Wireless communication occurs by way of telemetry means 58 transmits information externally to work station 62 and telemetry means 64 of work station 62 transmit information internally. The stimulation device may be made from a silicon material.

Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. It has been held that the recitation of an element is "adapted to" perform a function is not a positive limitation but only requires the ability to perform. It does not constitute limitation in any patentable sense. In re Hutchinson, 69 USPQ 138. In this case since the reference structurally meets the claim it is fully capable of performing the function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 19, 254 and 255 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy.

As discussed above, Bardy discloses the apparatus for treatment of intestinal dysfunction as claimed. Bardy however fails to disclose some of the specifics of the invention such as sensing capabilities and the use of hooks to hold the internal components in place. It is obvious that the pressure sensing components would be capable of sensing the patient's orientation due to the effect of gravity. When the patient is standing the pressure would be greater than when the patient is lying horizontally. Brady discloses the use of sutures and staples for holding the components in place. It is obvious that these elements have the capability of performing the same function as the hooks claimed by the applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus disclosed by Bardy to include orientation into the sensors measuring parameter and use hooks instead of staples for securing the components within the body.

Claims 48, 73, 74, 76, 77, 78, 79 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy in view of Rosar (USPN 6,223,083).

As discussed above, Bardy discloses the apparatus as claimed. Bardy however fails to disclose components involved in the telemetry of information. Rosar teaches an implantable medical device comprising capacitors, transceivers, receivers, and modulated signals for relaying information from an implantable medical device to external monitoring systems. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus disclosed by Bardy to incorporate the

Art Unit: 3738

components taught by Rosar to all the transfer of data from the implantable stimulation device to an external monitoring system.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Upon applicant's request for the clarification of claims 61-65 the Examiner states that these claims were rejected by Examiner Gilpin in Paper No. 8.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3738

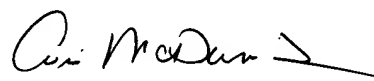
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
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KRL


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